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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,292	05/03/2000	ULRICH KLAR	SCH1742	1743

7590

02/08/2005

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,292

Applicant(s)

KLAR ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 September 0704.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Sept. 7, 2004 have been entered and considered carefully. A declaration by Klar under 37 CFR 1.132 was filed. Claims 13-30 have been canceled. Claims 1-12 and newly added claim 31 are pending.

2. The rejection of claims 1-12 under 35 USC 112 first paragraph is maintained for reason of record. In addition, a new matter rejection is made in view of the newly amended claims.

Applicants argued that the office has the burden of providing objective evidence that the disclosure is not commensurate in scope with the claims.

It has been explained in the previous office action that the chemical art is highly unpredictable. In the instant case, it is noted that the claimed scope is broadly encompassed by the term "aryl". This term was described on page 8 to be carbocyclic or heterocyclic radicals such as...etc. Please note that not only the use of "aryl" to include heterocyclic is contradictory to the understanding of the term by one skilled in the art (see Hackh's chemical dictionary), it is unclear how can a compound when R1a, R1b, R2a, R2b, R3, R4, R5, F8, R9, R10, R11, R12, R13b, R14b, R15a, R15b are all "aryl" can be made. The specification while provided examples for compounds wherein one of R10 or R11 is thiazol, oxazol, pyridine or benzthiazol, no provision can be found to any other moieties being "aryl" at any other positions. Please note that the instant compounds contain stereo hindered 16-membered ring system, the synthesis of any undetermined "aryl" on such ring system is not automatic but must be explicitly taught by the specification. Starting material and how to make must be taught and made available to the public. Absent of description and source, the public is offered mere language rather than enablement. *Exparte Moersch* 104 USPQ 122. *In re Howarth* 210 USPQ 689.

Claims 2-12 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims contain new matter and lacks antecedent basis for X is thiazol.

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Please note that while convolutedly when X is C R10R11 and one of the R10 or R11 is thiazol can be interpreted into the base claim, structurally, X can not be thiazol since a carbon linker will be missing were X is thiazol as claimed claim2.

This is a NEW MATTER rejection. Removal of all new matter is required. In re Russmussen 211 USPQ 325.

Claims 10-11 are self conflicting because the claims are drawn to process of making and pharmaceutical composition yet no dosage limitation was required. Since pharmaceutical composition can not be either ineffective nor toxic, enablement for such composition was not found in the specification. It is recommended that the dosage of therapeutically effective amount be incorporated in the claims.

3. Claims 1-12 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusing as to what is the scope of the claims. Please note that the dependent claims being drawn to X is thiazol, pyridyl etc. does not read on the base claim since the base claim has X being CR10R11 and R10 or R11 can be "aryl". Reading "aryl" to include thiazolyl is a distortion of the term. It is recommended that the limited moieties disclosed on page 8 be incorporated specification to obviate such ambiguity.

4. The rejection of claims 1-12 under 35 USC 103(a) over CA 132:293587 and Nicolaou et al. is maintained for reason of record.

Applicants' attempt to obviate the 103(a) rejection by submitting a declaration by Klar under 37 CFR 1.132 was not consistent with the amended claims. Please note that while Klar submitted a 132 declaration showing unexpected result wherein one of R2a or R2b is an alkyl longer than methyl, the claims have not been amended commensurate to the submission. Instead, the amended claims contain new matter.

5. Claims 1-8, 10 -11 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23-22 of

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compending SN 09/913,163 or claim 3 of compending Application No. 10/631,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of 09/913,163 are mere subsets of the instant genus in combination which is fully embraced by the instant claims, while the species of SN 10/631,011 is the instantly tested compounds (see claim 3, p.11, 7-ethyl species). A species and genus relationship is *prima facie* obvious especially when the generic claims having overlapping scope. There is no good reason for unjustified extension of time of the claims through species for which the unexpected result is based upon.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are urged to clearly demarcate all pending claims or file proper terminal disclaimers. Update of compending claims status is recommended to avoid double patenting rejections.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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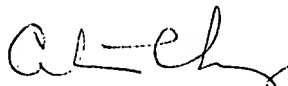
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 3, 2005



Celia Chang
Primary Examiner
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